

**REMARKS**

This communication is in Response to the Office Action mailed on July 9, 2008. Claims 27 and 36 have been amended. Support for these amendments generally comes from the specification, drawings, and claims as originally filed, but particularly at paragraphs [0037], [0038] and FIGS. 1, 8, 10, and 12. Claims 1-26, 37 and 46-47 were previously cancelled. Claims 27-36 and 38-45 are currently pending.

In view of the above amendments and below remarks, it is believed that the pending claims are in a condition for allowance. Reconsideration of the pending claims and an indication of allowance are therefore respectfully requested.

As an initial matter, the Applicants would like to thank Examiner Kasztejna for his time and effort during our telephonic interview on August 29, 2008. The Examiner's insight and comments were very helpful in formulating a response to the outstanding office action.

**Double Patenting**

Claims 27 and 36 were provisionally rejected on the ground of nonstatutory obviousness-type double patent as being unpatentable over claims 22-24 of copending Application No. 10/698,213. If necessary, a terminal disclaimer will be submitted after allowance of the present application to obviate this rejection in order to expedite issuance. The Applicants therefore request that this rejection be held in abeyance until claims are indicated as allowable.

**Rejection of the Claims Under 35. U.S.C. § 103**

Claims 27, 30-32, and 34 have been rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,231,591 to Ashvin H. Desai ("Desai") in view of U.S. patent No. 5,486,161 to Ronald G. Lax et al. ("Lax"). However, no combination of Desai and Lax discloses, teaches, or suggests all of the limitations in the claims. Independent claim 27 therefore does not read upon any combination of these references. Withdrawal of this rejection is therefore respectfully requested.

Amended claim 27 includes limitations to a method for delivering a denervating agent to a prostate gland that includes inserting an imaging apparatus into a rectum of a patient, "wherein the imaging apparatus is a shaft with a longitudinal axis that includes a hole at the distal tip, the shaft rotatably attached to a handle" and "rotating and moving the shaft with respect to the

prostate gland to position the distal end of the shaft in proximity to a second location of the prostate gland based on the one or more images while the shaft is still inserted into the rectum of the patient and wherein the shaft is also rotated relative to the handle.”

The combination of Desai and Lax does not teach, suggest, or disclose all of the elements of claim 27.

Desai teaches a hollow core needle that is inserted into a body for the delivery of various biological agents to a target area. Abstract. Desai includes the use of an endoscopic instrument to help guide the needle. Lax discloses a stylet ablation device for delivering energy or substances to the tissue. One embodiment of Lax is directed toward a radiofrequency ablation device that includes a rigid hollow needle and an RF electrode. As stated in a previous Office Action, however, “Desai and Lax et al. are silent with a wheel used to rotate the orientation of the needle.” October 31, 2007 Office action at 4. The combination of Desai and Lax, therefore, does not render independent claim 27 as obvious. Claims 28-29 and 30-35, which depend directly or indirectly from claim 27, are also no obvious for at least this same reason.

Independent claim 36 was rejected over Desai in view of Lax and in further view of Luther. As discussed above, no combination of Desai and Lax teach, suggest, or disclose a “system for delivering a denervating agent to a prostate gland” that includes “an imaging apparatus sized for insertion into a rectum of a patient to generate one or more images of a prostate gland, the imaging apparatus having a shaft with a longitudinal axis and formed with a hole, a handle, and a wheel fixed to the shaft and rotatably connected to the handle to permits rotation of the shaft relative to the handle and about the longitudinal axis while the shaft is inserted into the rectum.” Luther fails to remedy this deficiency.

The Office Action cites to Luther as disclosing “a needle having a wheel which permits rotation of the needle to a desired orientation.” Office Action, at 6. Luther does teach a hollow needle that can be “rotated by rotating the syringe barrel adapter.” However, the needle is not intended to be rotated while inserted in the patient. Rather, “rotation of the hollow needle 120 while the hollow needle 120 is positioned within a patient's vasculature presents the risk of injuring the patient with the rotating beveled tip 122.” Luther, col. 4, lines 13-17. When the needle is inserted into the patient Luther allows the “user to rotate the syringe barrel adapter 130 as required for convenience, without simultaneously rotating the hollow needle.” In other words, Luther allows the user to rotate the syringe barrel adapter 130 to a more convenient position

during the procedure without affecting the orientation of the needle that is inserted into the patient. The needle is rotatable in relation to the syringe barrel adapter 130, but is not a rotatable needle as disclosed, implemented, and claimed in the present invention. Luther therefore does not teach, suggest, or disclose all of the limitations of independent claim 36. Luther, in fact, teaches away from the present invention by stating that adjustment of the orientation for insertion of the needle when the needle is in the patient is dangerous. Luther does not cure the deficiencies of Desai and Lax. Withdrawal of this rejection is therefore respectfully requested.

Dependent claims 38-47 depend directly or indirectly on independent claim 36. These claims are therefore allowable for at least the same reasons as given above.

### **CONCLUSION**

In view of the foregoing amendments, Applicants respectfully request reconsideration and allowance of the claims as all rejections have been overcome. Early notice of allowability is kindly requested.

The Examiner is respectfully requested to contact the undersigned by telephone at 763.526.6363 or by e-mail to [scott.a.marks@medtronic.com](mailto:scott.a.marks@medtronic.com) with any questions or comments.

Please grant any extension of time, if necessary for entry of this paper, and charge any fee due for such extension or any other fee required in connection with this paper to Deposit Account No. 13-2546.

Respectfully submitted,

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